AUG - 2 2011

K103733

510(k) Summary of Safety and Effectiveness

Submission Information

Company:	United Orthopedic Corporation
Address:	No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan
Contact Person:	Fang-Yuan Ho, Regulatory Affairs Manager
	Phone:+886-3-5773351 ext. 212
	Fax:+886-3-5777156
Date Prepared:	December 15, 2010

Device Identification

Device Name:	U2 XPE Total Knee System
Common Name:	Semi-constrained total knee prostheses
Classification Name and Reference :	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560. This falls under the Orthopedics panel.
Device Product Code	JWH
Predicate Device:	1. "UNITED" U2 Total Knee system (K051640) 2. "UNITED" UKNEE Total Knee System (K021657) 3. "Zimmer" Prolong Highly Crosslinked Polyethylene CR Articular Surface Components (K013991) 4. "Howmedica Osteonic" Scorpio X3 Tibial Bearing Insert (K071991) 5. "Zimmer" NexGen Prolong All-Poly Patella (K072281) 6. "Howmedica Osteonics" Scorpio X3 Patellar components (K051997)

Intended Use

U2 XPE Total Knee System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device system is designed for cemented use only.

Device Description:

U2 XPE Total Knee System includes U2 XPE tibial inserts and U2 XPE patellar components of a Total Knee System.

U2 XPE tibial inserts are intended to be used with the cemented U2 femoral components (K051640) and the cemented U2 tibial tray (K051640) in total knee arthroplasty. U2 XPE tibial inserts will be made in Cruciate Retaining (CR) and Posteriorly Stabilized (PS) designs.

If replacement of the articular surface of the patella is required, U2 XPE patellar components are intended to be used with any one of the "UNITED" femoral components (K021657, K051640, K082424) in total knee arthroplasty. U2 XPE patellar components are available in Onset with three pegs and Inset with one peg designs. The all polyethylene patellar components are intended for implantation with bone cement only.

The geometric design and size distribution of U2 XPE tibial inserts are identical to the previously cleared tibial inserts of U2 Total Knee System (K051640). The geometric

design and size distribution of U2 XPE Onset patellar components and Inset patellar components are identical to the previously cleared U2 patellar components (K051640) and UKNEE patellar components (K021657) respectively. U2 XPE tibial inserts and patellar components are manufactured from irradiated UHMWPE which conform to ASTM F2565, while the UHMWPE raw material is in accordance with ASTM F648 and ISO 5834. The manufacturing processes are identical to the predicate devices tibial inserts and patellar components (K051640, K021657), except for the addition of irradiating the polyethylene and melt annealing steps to reduce free radicals of material. The irradiated UHMWPE material has been assessed according to the tests recommended in ASTM F2759.

Performance Data:

Testing and analysis includes locking strength, range of motion and constraint, fatigue strength, wear simulation test, and materials properties of the U2 XPE Total Knee System, have been completed as part of the design assurance process demonstrated that this device is safe and effective and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

United Orthopedic Corporation
% Mr. Fang-Yuan Ho,
Regulatory Affairs Manager
No. 57, Park Ave. 2, Science Park
Hsinchu, 300 Taiwan

AUG - 2 2011

Re: K103733
Trade/Device Name: U2 XPE Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: May 24, 2011
Received: June 8 2011

Dear Mr. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K103733

Device Name: U2 XPE Total Knee System

Indications for Use:

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

This device system is designed for cemented use only in the U.S.A.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103733